K091194
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EV MED TECH LLC

510(k) SUMMARY of Safety and Effectiveness

(Pursuant to 21 CFR 807.92)
April 21, 2009

MAY 18 2009

I. GENERAL

A. Submitted By: Evolution Medical Technologies LLC.
3439 NE Sandy Blvd.
Suite # 142
Portland, Oregon 97232

B. Contact Person John Manning
President

C. Proprietary Name: Algiseal Pad

D. Classification Name: Unknown

E. Classification: Unclassified

FDA CDRH DMC

APR 23 2009

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II. DEVICE INFORMATION SUMMARY

A. Predicate Device

Kalginate by DeRoyal	(K941176) (K914779)
Neptune Pad by TZ Medical	(K040208)

B. Device Intended Use

Algiseal products are used to promote the rapid control of bleeding and hemostasis for wounds, at the skin surface for arterial/vascular sites and in patients on anticoagulation therapy. May also be used in conjunction with a facility approved, post-hemostasis site dressing.

C. Device Description

Algiseal Pad – (Varying size, with and without permeable adhesive backing, packaged sterile) Pads may be used alone as a wound dressing. The Pad may also be used with manual pressure or FDA cleared mechanical pressure devices to provide rapid control of bleeding and hemostasis at the skin surface. May be used in conjunction with a facility approved, post-hemostasis site dressing.

III. SUBSTANTIAL EQUIVALENCE TESTING SUMMARY

The Evolution Medical Technologies LLC Algiseal products have been tested and are considered safe and effective. Testing and support data are on file to demonstrate substantial equivalence to predicate devices. Data demonstrates there are no new risks associated with the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Evolution Medical Technologies, LLC
% Mr. John Manning
President
3439 NE Sandy Boulevard, Suite 142
Portland, Oregon 97232

Re: K091194
Trade/Device Name: Algiseal Pad (Various sizes, with and without permeable adhesive backing, sterile, single use only)
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 21, 2009
Received: April 23, 2009

Dear Mr. Manning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K091194**

Device Name:

Algiseal Pad (Various sizes, with and without permeable adhesive backing, sterile, single use only)

Indications For Use:

Algiseal Pad (calcium alginate pad alone and pad with permeable adhesive backing): Algiseal Pad is used to promote the rapid control of bleeding and provide hemostasis for lacerations, abrasions, vascular access sites and following surgical incision. It can be used to achieve hemostasis at the skin surface for arterial/venous catheterization/tubes, needle puncture, hemodialysis patients and in patients on anticoagulation therapy. May be used in conjunction with a facility approved, post-hemostasis site dressing.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091194